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EXHIBIT 25

DECLARATION OF ROBERT J. KUHN, PHARM. D.

I, Robert J. Kuhn, declare as follows:

1. My name is Robert J. Kuhn. I am a professor at the University of Kentucky College of Pharmacy. I received a doctor of pharmacy degree in 1984 from the University of Texas, Austin. I specialize in pediatric pharmacy and pulmonary drug delivery and have done extensive research on cystic fibrosis ("CF"). I have been an invited speaker at the North American Cystic Fibrosis Conference, European Cystic Fibrosis Conference, Cystic Fibrosis Foundation, and National Cystic Fibrosis Caretakers Conference, among many others. I am a recipient of a fellowship from the American Society of Hospital Pharmacists Pediatric Pharmacotherapy. I have served as a reviewer of the journals *Clinical Pharmacy, Drug Intelligence and Clinical Pharmacy* and *American Journal of Hospital Pharmacy*. My education, training, and experience in the field of pharmacy, and, particularly, with respect to pediatric pharmacy and Cystic Fibrosis are set forth in detail in the true and correct copy of my curriculum vitae, attached as Exhibit A, which I incorporate as if set forth fully herein.

2. Pseudomonas aeruginosa (Pa) is a common bacteria that causes chronic lung infections in patients with CF. Approximately 90 percent of patients with CF get a Pa infection at some point during their lives. Treatment of Pa infections with oral antibiotics is often ineffective. Treatment with intravenous antibiotics is more effective, but is associated with an increased risk of ototoxicity (having a toxic effect on the structures of the ear, especially on its nerve supply) and nephrotoxicity (having a toxic effect on the kidneys).

3. Another treatment approach is to administer aminoglycosides (broad spectrum antibiotics) directly to the lungs through inhalation therapy. Inhalation therapy is accomplished by preparing the antibiotic in a sterile solution and then aerosolizing the solution with a

nebulizer. The aerosolized antibiotic solution can then be inhaled into the lungs, which is the source of the Pa infection. While inhalation therapy has numerous theoretical advantages over oral and intravenous delivery, there are several critical considerations which must be addressed when attempting to treat CP patients in this manner.

4. One of the most important considerations is how the antibiotic will be distributed in the lungs. Because of the effects of the disease, physiologic deposition of drugs in the lungs of a CF patient varies more than in the lung of a healthy person. In part because of this increased variability, clinical studies involving CF patients are the only way to accurately measure how drugs are distributed in the lungs of a CF patient.

5. Particle size and mode of administration have been shown to play an important role in how drugs are delivered in the lungs. Particle size is a major factor in influencing drug deposition in the lungs and, therefore, a major challenge for effective inhaled antibiotic therapy. In CF patients, drug particles need to reach the bronchioles (fine, thin-walled, tubular extensions of a bronchus), where the disease process usually begins, and then extend to the bronchi (plural of bronchus, meaning either of two main branches of the trachea, leading directly to the lungs). .

6. The use of different aerosol delivery devices can result in variations of particle sizes of the same drug. In other words, the same drug delivered by two different nebulizers can produce different particle sizes and, therefore, different distribution of drugs in the lungs. Because particle size is such an important factor in drug distribution, use of different nebulizers may significantly change the distribution of an aerosolized antibiotic in CF patients. The result may be the CF patient receiving too much or too little of the antibiotic. In the first instance, the risk of toxicity is increased. In the second instance, the risk of continued infection is increased.

7. The pH level and the ionic strength (concentration of ions in a solution) of the aerosolized antibiotic are also important considerations. The introduction of the wrong pH solution into a CF patient's lungs can cause coughing, mucosal irritation, and bronchospasm. Similarly, solutions which are hyperionic (high concentration of ions) may induce coughing and irritation of the airways.

8. The same is also true if the aerosolized solution is not sterile or contains improper preservatives, buffers, stabilizing agents, or other additives. In addition to causing such side effects as coughing and bronchoconstriction, use of these substances can alter particle size, which, as noted above, is a critical factor in determining drug deposition. The use of inactive ingredients in an aerosolized antibiotic solution which have not been clinically tested in CF patients may effect the distribution and deposition of the drug in the lungs. Such an effect would may have an impact on the drug's safety and efficacy.

9. Based on the above, the only way to determine whether an aerosolized antibiotic treatment is safe and effective in CF patients is to conduct clinical trials with CF patients. The distribution of an aerosolized antibiotic in a CF patients' lungs is a very complex process and depends on numerous factors which cannot be replicated *in vitro* (in an artificial environment outside the living organism; e.g., a test tube).

10. Clinical trials have been performed on TOBI®, a nonpyrogenic, preservative-free, pH-adjusted formulation of tobramycin solution for inhalation administered with the PARI LCPlus jet nebulizer.

11. The need for clinical testing is essential to determine whether a compounded tobramycin solution that is aerosolized with a PARI *e*Flow nebulizer is safe and effective when used by CF patients with Pa infections. There can be no other way to adequately determine the

safety and efficacy of such a product. In the absence of such clinical testing, the doctor can not be sure that the distribution and deposition of the aerosolized tobramycin solution is sufficient to treat the Pa infection but not so great as to increase the risk of toxicity to the patient.

12. Similarly, the only way to determine whether a compounded tobramycin solution that is aerosolized with a PARI *e*Flow nebulizer is equivalent and comparable in safety and efficacy to TOBI® aerosolized with the PARI LCPlus nebulizer is through controlled clinical testing.

13. Beginning on October 14, 2004, I will be attending the 18th Annual North American Cystic Fibrosis Conference in St. Louis, Missouri. This conference is one of the largest CF medical and scientific conferences in the world and hundreds of health care professionals and research scientists interested will be in attendance.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT. EXECUTED ON SEPTEMBER __, 2004.

Robert J. Kuhn, PharmD